UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. S2- 4:19-cr-00591-ERW-NAB
	)	
ABDUL NAUSHAD, M.D., and WAJIHA NAUSHAD,	)	
	)	
Defendants.	)	

SECOND SUPERSEDING INDICTMENT

The Grand Jury charges that:

BACKGROUND

1. At all times relevant to this indictment, defendant Abdul Naushad ("Dr. Naushad") was a medical doctor, licensed to practice medicine in the state of Missouri. Between 2005 and the present, Dr. Naushad has owned and operated a number of pain management clinics in Missouri, which clinics operated under the names "Advanced Pain Center" or "Advanced Pain Centers." The clinics were often simply referred to as "APC" and were located in Cape Girardeau, Eureka, Farmington, Festus, Hayti, Kennett, Poplar Bluff, and Sullivan, Missouri. At certain times, Dr. Naushad simultaneously owned and operated as many as six APC clinics in Missouri.

2. At all times relevant to this indictment, defendant Wajiha Naushad was the wife of Dr. Naushad, and she and Dr. Naushad jointly managed the above described pain clinics. Among other tasks, Wajiha Naushad was responsible for ordering and managing the use of certain medical devices and drugs at the pain clinics.

3. Dr. Naushad has been an approved Medicare and Medicaid provider since approximately October 2002. At times, Dr. Naushad has also been a provider for or has submitted reimbursement claims to other health care benefit programs, including Tricare and private health insurance companies.

Relevant Medicare Provisions

4. The Medicare Program is a federal health benefits program which the United States Department of Health and Human Services (HHS) administers through the Centers for Medicare and Medicaid Services (CMS). Medicare Part B reimburses health care providers for covered health care services provided to eligible elderly and disabled patients in outpatient settings. Medicare will only reimburse health care providers for drugs or medical devices that the United States Food and Drug Administration ("FDA") has approved. As relevant to this indictment, the "Medicare Benefit Policy Manual" provides that Medicare will pay for medical "[d]evices approved by the FDA through the Pre-Market Approval (PMA) process" or through other FDA approval processes. Chapter 14, Section 10, entitled "Coverage of Medical Devices."

5. CMS acts through fiscal agents, called Medicare Administrative Contractors ("MAC"), which are agents of CMS for Medicare Part B. The MACs are private entities, such as insurance companies, that review claims and make payments to health care providers for services rendered to Medicare beneficiaries. Wisconsin Physicians Service Insurance Corporation ("WPS") is the MAC for Eastern Missouri and thus processes reimbursement claims submitted by Advanced Pain Centers.

6. To receive Medicare reimbursement, physicians and other qualified health care providers must execute a written provider agreement. The provider agreement obligates the health care providers to know, understand, and follow all Medicare regulations and rules.

7. As part of the application process, Dr. Naushad signed a CMS-8551 form that informed him of the penalties for falsifying information to gain or maintain enrollment in the Medicare program and of the penalties for falsifying information when seeking reimbursement from the Medicare program. Under Section # 14, entitled "Penalties for Falsifying Information," the Medicare provider agreement states:

> 18 U.S.C. 1035 authorizes criminal penalties against individuals in any matter involving a health care benefit program who knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact; or makes any materially false, fictitious, or fraudulent statement or entry, in connection with the delivery of or payment for health care benefits, items, or services. . . .
>
> 18 U.S.C. 1347 authorizes criminal penalties against individuals who knowing[ly] and willingly execute or attempt, to execute a scheme or artifice to defraud any health care benefit program, or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by or under the control of any health care benefit program in connection with the delivery of or payment for health care benefits, items, or services. . . .

8. The provider agreement signed by Dr. Naushad also contained a "Certification Statement," (Section #15) that provided in part: "I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity." Dr. Naushad signed provider agreements containing the sections entitled "Penalties for Falsifying Information" and "Certification Statement" on four separate occasions: September 20, 2006; July 27, 2009; January 12, 2010 and May 18, 2010.

9. After the successful completion of the application process, Dr. Naushad was assigned a unique provider number, which is a necessary identifier for billing services to Medicare. Additionally, Dr. Naushad was provided access, at no cost, to regulations and other materials governing Medicare reimbursement.

10. Medicare providers must retain medical records for the length of time required by state law or five years from the date of discharge if there is no requirement in state law. Missouri statutes require that physicians maintain patient records for a minimum of seven years from the date when the last professional services were rendered.

Relevant Medicaid Provisions

11. In addition to being a Medicare provider, at all relevant times, Dr. Naushad was enrolled in the Missouri Medicaid Program, which HHS, through CMS, administers at the federal level. The Medicaid Program is a federal and state funded program that reimburses health care providers for health services provided to eligible low income individuals. The Missouri Medicaid Program, now called MO HealthNet, is administered by the Missouri Department of Health and Human Services. With certain exceptions not applicable here, the Medicaid Program only reimburses for FDA approved drugs and medical devices.

12. A Medicaid provider must enter into a written agreement with MO HealthNet to receive reimbursement for medical services provided to Medicaid recipients and must agree to abide by MO HealthNet's regulations in rendering services and billing for those services.

The Federal Food, Drug, and Cosmetic Act

13. At all relevant times, the United States Food and Drug Administration was the federal agency responsible for protecting the health and safety of the American public by, among other things, enforcing the provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*.

14. The FDA's responsibilities included regulating the manufacturing, labeling, and distribution of medical devices shipped in interstate commerce to ensure the devices were safe and effective for their intended uses and had labeling that contained true and accurate

information. The FDA carried out its responsibilities by enforcing the FDCA and related laws and regulations.

FDA Approval of Medical Devices

15. The FDCA defined a "device" as, among other things, "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or . . . intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h).

16. A "prescription device" was a device that, because of any potential for harmful effect, or the method of its use, or the collateral measures necessary to its use, was not safe except under the supervision of a practitioner licensed by law to direct the use of such device. 21 C.F.R. § 801.109.

17. Medical devices were classified into one of three categories, Class I, II, or III. 21 U.S.C. § 360c. Devices that were first marketed on or after May 28, 1976, were Class III devices by operation of law. 21 U.S.C. § 360c(f)(1). With certain exemptions not applicable here, all Class III medical devices were deemed to be adulterated if they had not received PMA from the FDA. 21 U.S.C. § 351(f)(1)(B).

18. An application for PMA described in great detail how the device worked, how it was manufactured, and precisely what would be stated on the label and labeling. As part of the process, FDA had to approve the manufacturing process, components and ingredients, label and

labeling, and packaging set forth in the application. 21 U.S.C. § 360e(c)(1); 21 C.F.R. § 814.20. The approval process required, among other things, that a manufacturer provide the proposed text of the labeling for the product. 21 U.S.C. § 360e(c)(1)(F); 21 C.F.R. § 814.20(b)(10).

19. A device was adulterated if, among other things, it was a Class III device pursuant to 21 U.S.C. § 360c(f), and was therefore required under 21 U.S.C. § 360e(a) to have, in effect, an approved Pre-Market Application for Approval, and did not have such an approval in effect. 21 U.S.C. § 351(f).

Labeling and Misbranding

20. The FDCA defined the term "label" as a display of written, printed, or graphic matter upon the immediate container of any article. 21 U.S.C. § 321(k). The term "labeling" was broader, and included all labels, as well as other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. 21 U.S.C. § 321(m).

21. A device was misbranded if, among other things:

(a) its labeling failed to bear adequate directions for use, 21 U.S.C. §352(f)(1); or

(b) its labeling failed to bear adequate warnings against unsafe dosage or methods or duration of administration or application, in such manner and form, as were necessary for the protection of users, 21 U.S.C. §352(f)(2).

22. "Adequate directions for use" meant that the directions were sufficient for a layperson to safely use the device and for the purposes for which it was intended. Directions under which a layperson could use a device safely could not be written for a prescription device because such devices could, by definition, only be used safely at the direction, and under the

supervision, of a licensed practitioner. FDA-approved prescription devices with their approved labeling were exempt from having adequate directions for use by a layperson only if several conditions were met. 21 C.F.R. §801.109. Unapproved prescription devices that did not meet all the conditions for an exemption from the requirement of having adequate directions for use were necessarily misbranded.

FDA-Approved Orthovisc

23. Orthovisc, a Class III prescription medical device, was manufactured by Anika Therapeutics and was approved by the FDA in February 2004 for sale and use in the United States ("FDA-approved Orthovisc"). FDA-approved Orthovisc is a sterile, clear, viscoelastic solution of hyaluronan contained in a single use syringe. Hyaluronan is a natural chemical found in the human body. High amounts of hyaluronan are found in the joint tissues and in the fluid that fills the joints and acts like a lubricant and a shock absorber in the joints. Hyaluronan is needed for joints to work properly.

24. FDA-approved Orthovisc is approved for use in the United States for patients with osteoarthritic pain in the knees who do not get adequate pain relief from simple pain relievers, like acetaminophen, or from exercise and physical therapy. In the United States, Orthovisc has been approved by FDA for use only in the knee joint. Orthovisc is injected directly into the knee joint at intervals prescribed by the treating physician. FDA has only approved Orthovisc for use under the supervision of a licensed practitioner.

25. The label on the FDA-approved Orthovisc box is red, blue and white and the words "ORTHOVISC, HIGH MOLECULAR WEIGHT HYALURONAN" prominently appear on the label. The labeling on the FDA-approved Orthovisc contains warnings and precautions related to the safe and effective use of Orthovisc; this labeling was approved by the FDA.

26. Anika Therapeutics also manufactures a non-FDA approved foreign version of Orthovisc, hereinafter "non-FDA-approved Orthovisc" or "foreign Orthovisc." This non-FDA approved Orthovisc or foreign Orthovisc has not been approved by the FDA, and as a result, the device's safety and efficacy are unknown.

27. The label on the box containing the foreign Orthovisc has a white background with interlocking blue, yellow, and green rings. The labeling on the foreign Orthovisc is different and much less extensive than the labeling on the FDA-approved Orthovisc. Because of its inadequacy, the foreign Orthovisc labeling fails to meet all the conditions for exemption from the requirement of having adequate direction for use pursuant to 21 C.F.R. §801.109. For example, absent from the labeling for the foreign Orthovisc are warnings and precautions that are present on the FDA approved labeling, including: a warning not to use certain substances on the skin prior to the administration of the Orthovisc, advice not to freeze the Orthovisc and to store it at room temperature, information concerning the safety and effectiveness of Orthovisc in pregnant women and children, and information about the effects of the Orthovisc on patients. In addition, the foreign Orthovisc failed to limit application of the device to the knee joint, which is the only current indication approved in the U.S. This information was not on the labeling of the foreign Orthovisc and not immediately available to Dr. Naushad and others who administered the foreign Orthovisc to patients at his clinics.

Defendants' Purchase of Non- FDA Approved Orthovisc

28. In or about February 2007, CP Logistics shipped hyaluronic acid sodium from "St. Maarten, Netherland Antilles" to the Advanced Pain Center in Popular Bluff, Missouri. On February 7, 2007, the FDA's New York District Office sent a "Notice of FDA Action" to the clinic, advising that the hyaluronic acid sodium was refused admission into the United States

because the hyaluronic acid sodium "appears to be a new drug without an approved new drug application. Drug is available in the U.S. and therefore not permitted under the personal use exemption. Almost all drugs are considered new drugs. . . .The U.S. Customs Service will cause the entire shipment to be returned to the sender or destroyed if the sender is unknown."

29. After being informed of the 2007 FDA notice, the defendants continued to order non-FDA approved devices from foreign companies. Beginning in or about 2010 and continuing to in or about 2017, the defendants purchased foreign Orthovisc online from a company called Willow Creek Enterprises Limited ("Willow Creek").

30. Related to these foreign Orthovisc purchases, the defendants received fax cover sheets, an "Orthovisc Order Form," packing slips, and invoices, all of which indicated that Willow Creek was located in Hamilton, Ontario, Canada. The fax cover sheet further stated that the "Orthovisc, ships from UK, from $55/syringe." On a 2011 order form, "Dr. Abdul Naushad MD, Advanced Pain Center" is listed as the customer, "Wajiha Naushad" is listed as the contact person, and the defendants' home address is listed. A photo of the box for the foreign Orthovisc is also shown on the order form.

31. At all times relevant to this indictment, Willow Creek worked with a company called World Medical Ltd, which is incorporated in England. In some instances, when Willow Creek received an Orthovisc order from the defendants, the president of Willow Creek would contact World Medical and arrange to have the foreign Orthovisc shipped, by Parcel Force, from World Medical into the United States.

32. After the initial delivery into the United States, the foreign Orthovisc was typically transported by the United States Postal Service ("USPS") from New York State and

delivered to the defendants' home in St. Louis County, Missouri. The chart below reflects some of the deliveries of foreign Orthovisc to the defendants' home:

USPS International Tracking Number	Date of Delivery	Destination	Origin
EM056560567CA	8/12/2015	St. Louis, MO	Canada
EM057839239CA	12/30/2015	St. Louis, MO	Canada
EM057839260CA	1/4/2016	St. Louis, MO	Canada
EM057839273CA	1/4/2016	St. Louis, MO	Canada
EM058419493CA	3/25/2016	St. Louis, MO	Canada
EM058419604CA	7/1/2016	St. Louis, MO	Canada
EM058419618CA	7/1/2016	St. Louis, MO	Canada
EM059839656CA	7/20/2016	St. Louis, MO	Canada
EM059839673CA	7/21/2016	St. Louis, MO	Canada
CX580318933CA	11/21/2016	St. Louis, MO	Canada
CX580318964CA	11/23/2016	St. Louis, MO	Canada

33. On several occasions, defendant Wajiha Naushad personally accepted and signed for the receipt of the foreign Orthovisc delivered to her home.

34. Dr. Naushad received Willow Creek invoices, reflecting a purchase price of between $37.00 and 55.00 per unit for the foreign Orthovisc. During the same period of time, the cost of FDA-approved Orthovisc was $110 to $154 per unit. The defendants paid Willow Creek with checks drawn on a Heartland or Midland Bank account (# 4176) and a Bank of America account (# 0160), in the name of Advanced Pain Centers. Dr. Naushad's name is listed on the "AUTHORIZED SIGNATURE" line on the checks, which were often in the amount of $4500.00 or $4950.00.

Defendants' Delivery to and Use of Foreign Orthovisc at the APC Clinics

35. After receiving the foreign Orthovisc at their residence, the defendants delivered the foreign Orthovisc to the APC clinics when APC employees notified them that Orthovisc was needed at one or more of the clinics. Either Dr. Naushad or Wajiha Naushad would personally deliver the foreign Orthovisc to the APC clinics or cause the foreign Orthovisc to be transported

and delivered to the clinics as needed. Notably, APC employees were responsible for ordering other needed drugs and supplies, which were received and stored at the APC clinics. However, APC employees were not authorized to order the foreign Orthovisc.

36. After the defendants delivered the foreign Orthovisc to the clinics, the APC doctors and advanced nurse practitioners injected the foreign Orthovisc into patients' knees. On some occasions, Dr. Naushad personally injected or supervised the injection of the foreign Orthovisc into patients at the APC clinics.

37. The defendants did not inform anyone at the clinics, including doctors, nurse practitioners, or other APC employees, that they were purchasing foreign Orthovisc from outside the United States. Likewise, the defendants did not inform the patients that they were receiving treatment with a non-FDA-approved device. Nor did the patients receive any financial benefit or discount from the defendants' use of the foreign Orthovisc. The defendants were the only ones to financially benefit from using the foreign Orthovisc.

38. The medical records of several APC patients include the lot number of the Orthovisc that was injected into these patients. A lot number on the label of foreign Orthovisc purchased by the defendants indicates that the foreign Orthovisc was to be sold in one or more of the following countries: Austria, Croatia, Cyprus, Egypt, Germany, Hungary, Iraq, Italy, Malaysia, Oman, Philippines, Portugal, Singapore, Spain, United Kingdom, and the United Arab Emirates.

COUNT 1
18 U.S.C. § 371
Conspiracy

39. Paragraphs 1 to 38 are re-alleged and incorporated by reference as if fully set out herein.

40. From in or about 2007 to in or about 2017, in the Eastern District of Missouri and elsewhere,

ABDUL NAUSHAD, M.D.,
and
WAJIHA NAUSHAD,

the defendants herein, and others known and unknown, willfully and knowingly did combine, conspire, confederate, and agree together, and with each other, to defraud the United States and to commit offenses against the United States, that is,

a. to interfere and obstruct the lawful government functions of the FDA through deceit, craft or trickery, and by means that are dishonest, that is, by interfering with and obstructing the FDA's regulation of medical devices, including Orthovisc, and the FDA's enforcement of the FDCA prohibition against the receipt in interstate commerce and delivery thereafter of adulterated and misbranded devices;

b. with the intent to defraud and mislead, to receive into interstate commerce and to deliver for pay or otherwise misbranded and adulterated devices, in violation of 21 U.S.C. § 331(c), 21 U.S.C. §333(a)(2), and 18 U.S.C. § 2; and

c. to knowingly and willfully execute and attempt to execute a scheme and artifice to defraud a health care benefit program, in connection with the delivery and payment for health care benefits, items, and services, in violation of 18 U.S.C. §§1347(a)(1).

PURPOSE OF THE CONSPIRACY

41. The purpose of the conspiracy was for the defendants:

a. to purchase from their co-conspirators and to have delivered to them in the United States non-FDA approved Orthovisc;

b. to deliver and proffer the delivery of the non-FDA approved Orthovisc to others;

c. to administer the non-FDA approved Orthovisc to their patients without the patients' knowledge or consent; and

d. to receive reimbursement from Medicare and Medicaid for the non-FDA approved Orthovisc while knowing Medicare and Medicaid would not pay for non-FDA approved devices.

MANNER AND MEANS OF THE CONSPIRACY

42. It was part of the conspiracy that the defendants ordered foreign non-FDA approved medical devices from companies located outside the United States, received the medical devices in interstate commerce, and subsequently delivered the medical devices to their clinics.

43. It was further part of the conspiracy that the defendants took affirmative steps to conceal the purchase, receipt, delivery, and use of the non-FDA approved Orthovisc, including among other acts, having the non-FDA approved Orthovisc delivered to their residence and not informing APC doctors, nurse practitioners, patients, or Medicare and Medicaid that the Orthovisc was not approved by the FDA.

44. It was further part of the conspiracy that the defendants did not purchase or use FDA approved Orthovisc which was readily available in the United States because they derived more revenue from the lower cost non-FDA approved Orthovisc.

45. It was further part of the conspiracy that the defendants submitted and caused to be submitted false and fraudulent reimbursement claims to Medicare and Medicaid for non-FDA

approved Orthovisc, although they knew Medicare and Medicaid would not pay for non-FDA approved devices.

OVERT ACTS

46. In furtherance of the conspiracy, and to affect the objects of the conspiracy, the following overt acts among others were committed in the Eastern District of Missouri:

a. On or about August 12, 2015, "A. Naushad" received and signed for a package, sent from Willow Creek and delivered to the residence of Dr. Naushad and Wajiha Naushad.

b. On or about September 17, 2015, Dr. Naushad caused a Midland States Bank check to be issued to Willow Creek Enterprises Limited in the amount of $4950.

c. On or about January 4, 2016, Wajiha Naushad received and signed for a delivery of a package to her residence from Willow Creek.

d. On or about January 26, 2016, Dr. Naushad caused a Bank of America check to be issued to Willow Creek Enterprises Limited in the amount of $4950.

e. On or about June 17, 2016, Dr. Naushad injected non-FDA approved Orthovisc into Patient S.M.

f. On or about July 20, 2016, Wajiha Naushad received and signed for a delivery of a package to her residence from Willow Creek.

g. On or about September 25, 2016, Dr. Naushad caused a Midland States Bank check to be issued to Willow Creek Enterprises Limited in the amount of $4500.

h. On or about October 26, 2016, Dr. Naushad injected non-FDA approved Orthovisc into Patient T.M.

All in violation of Title 18, United States Code, Section 371.

COUNTS 2 to 7
Receipt in Interstate Commerce and Delivery and Proffered Delivery of a Misbranded Device with the Intent to Defraud and Mislead
21 U.S.C. §§ 331(c) and 333(a)(2) and 18 U.S.C. § 2

47. Paragraphs 1 to 38 and 42 to 46 are re-alleged and incorporated herein by reference as if fully alleged herein.

48. On or after the dates indicated below as to each count, in the Eastern District of Missouri, and elsewhere,

ABDUL NAUSHAD, M.D.,
and
WAJIHA NAUSHAD,

the defendants herein, with the intent to defraud and mislead, did receive, and caused to be received, in interstate commerce and did deliver and proffer, and caused to be delivered and proffered, for pay or otherwise, a misbranded device, specifically non-FDA approved Orthovisc, that was misbranded within the meaning of 21 U.S.C. §352(f)(1) and (2) in the following ways:

a. the labeling failed to bear adequate directions for use; and

b. the labeling failed to bear adequate warnings:

COUNT	DATE	SHIPPED FROM	MISBRANDED DEVICE
2	8/12/15	Canada	Non-FDA approved Orthovisc, 90 filled syringes
3	12/30/15	Canada	Non-FDA approved Orthovisc, 135 filled syringes
4	3/25/16	Canada	Non-FDA approved Orthovisc, 90 filled syringes
5	7/1/16	Canada	Non-FDA approved Orthovisc, 90 filled syringes
6	7/20/16	Canada	Non-FDA approved Orthovisc, 90 filled syringes
7	11/21/16	Canada	Non-FDA approved Orthovisc, 90 filled syringes

All in violation of Title 21, United States Code, Sections 331(c), 333(a)(2); and Title 18 United States Code, Section 2.

COUNTS 8-13
Receipt in Interstate Commerce and Delivery and Proffered Delivery of an Adulterated Device with the Intent to Defraud and Mislead
21 U.S.C. §§ 331(c) and 333(a)(2) and 18 U.S.C. § 2

49. Paragraphs 1 to 38 and 42 to 46 are re-alleged and incorporated herein by reference as if fully alleged herein.

50. On or after the dates indicated below as to each count, in the Eastern District of Missouri, and elsewhere,

ABDUL NAUSHAD, M.D.,
and
WAJIHA NAUSHAD,

the defendants herein, with the intent to defraud and mislead, did receive, and caused to be received, in interstate commerce and did deliver and proffer, and caused to be delivered and proffered, for pay or otherwise, an adulterated device, specifically non-FDA approved Orthovisc, that was adulterated within the meaning of 21 U.S.C. 351(f)(1)(B):

COUNT	DATE	SHIPPED FROM	ADULTERATED DEVICE
8	8/12/15	Canada	Non-FDA approved Orthovisc, 90 filled syringes
9	12/30/15	Canada	Non-FDA approved Orthovisc, 135 filled syringes
10	3/25/16	Canada	Non-FDA approved Orthovisc, 90 filled syringes
11	7/1/16	Canada	Non-FDA approved Orthovisc, 90 filled syringes
12	7/20/16	Canada	Non-FDA approved Orthovisc, 90 filled syringes
13	11/21/16	Canada	Non-FDA approved Orthovisc, 90 filled syringes

All in violation of Title 21, United States Code, Sections 331(c), 333(a)(2); and Title 18 United States Code, Section 2.

COUNTS 14-24
Health Care Fraud Scheme
18 U.S.C. §§1347(a)(1) and 18 U.S.C. § 2

51. The allegations contained in paragraphs 1 to 38 and 42 to 46 of this Indictment are re-alleged and incorporated by reference as if fully set out herein.

Description of Health Care Fraud Scheme

52. It was part of a scheme and artifice to defraud health care benefit programs that from in or about 2007 to in or about 2017, the defendants purchased foreign, non-FDA-approved medical devices, including hyaluronic acid sodium and Orthovisc, from foreign countries and thereby caused it to be illegally imported into the United States.

53. It was further part of the scheme and artifice to defraud that the defendants concealed the illegal purchases of non-FDA approved Orthovisc from the FDA, Medicare, Medicaid, and other regulatory agencies. Moreover, the defendants did not disclose on the patient informed consent forms nor otherwise inform their patients that non-FDA approved Orthovisc was to be injected into their bodies.

54. It was further part of the scheme and artifice to defraud that from in or about 2010 to in or about 2017, the defendants submitted, or caused to be submitted, reimbursement claims to insurers which falsely and fraudulently represented that the patients identified in the claims received FDA-approved Orthovisc, when the defendants knew the patients had received non-FDA-approved Orthovisc and further knew that the insurers would not pay for non-FDA-approved drugs or devices.

55. It was further part of the scheme and artifice to defraud that the defendants used or caused to be used CPT code J7324 on reimbursement claims to mislead and deceive insurers into believing that FDA-approved Orthovisc was provided to patients. CPT code J7324 is the

alpha-numeric code used by health care providers to request reimbursement from insurers for injections of FDA-approved Orthovisc.

56. On or about the dates indicated below, in the Eastern District of Missouri,

ABDUL NAUSHAD, M.D.,
and
WAJIHA NAUSHAD,

the defendants herein, knowingly and willfully executed and attempted to execute, the above described scheme or artifice to defraud the Medicare and Medicaid Programs, health care benefit programs, in connection with the delivery and payment for health care benefits, items, and services, that is, the defendants submitted, and caused the submission, of reimbursement claims to health care benefit programs, for misbranded and adulterated medical devices, to wit, non-FDA approved Orthovisc:

COUNT	PATIENT	DATE OF SERVICE	DATE CLAIM SUBMITTED	CPT CODE ON CLAIM	INSURER
14	D.H.	8/24/2015	9/2/2015	J7324	Medicare/Medicaid
15	D.B.	12/31/2015	1/13/2016	J7324	Medicare
16	D.B.	2/25/2016	3/4/2016	J7324	Medicare
17	S.M.	6/3/2016	6/13/2016	J7324	Medicare/Medicaid
18	S.M.	6/17/2016	6/24/2016	J7324	Medicare/Medicaid
19	M.G.	6/17/2016	6/28/2016	J7324	Medicare/Medicaid
20	M.G.	7/1/2016	7/12/16	J7324	Medicare/Medicaid
21	M.G.	7/22/2016	7/29/2016	J7324	Medicare/Medicaid
22	T.M.	10/26/2016	2/14/2017	J7324	Medicare
23	T.M.	11/30/2016	1/6/2017	J7324	Medicare
24	A.E.	3/23/2017	4/3/2017	J7324	Medicare

All in violation of Title 18, United States Code, Section 1347(a)(1) and Section 2.

FORFEITURE ALLEGATION

The Grand Jury further finds by probable cause that:

1. Pursuant to Title 18, United States Code, Section 982(a)(7), upon conviction of an

offense in violation of Title 18, United States Code, Sections 1347 as set forth in Counts 14 through 24, the defendants shall forfeit to the United States of America any property, real or personal, that constitutes or is derived from gross proceeds traceable to the commission of the offense.

2. Pursuant to Title 21, United States Code, Section 334 and 28, United States Code, Section 2461, upon conviction of an offense in violation of Title 21, United States Code, Section 331 as set forth in Counts 2 through 13, any article of food, drug, or cosmetic that is misbranded or adulterated when introduced into or while in interstate commerce is subject to forfeiture.

3. Subject to forfeiture is a sum of money equal to the total value of any property, real or personal, constituting or derived from any proceeds traceable to said offense.

4. If any of the property described above, as a result of any act or omission of the defendant:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of the court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be divided without difficulty,

the United States of America will be entitled to the forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p).

A TRUE BILL.

_____
FOREPERSON

CARRIE COSTANTIN
Attorney for the United States
Acting Under Authority
Conferred by 28 U.S.C. § 515

_____
DOROTHY L. McMURTRY, #37727MO
Assistant United States Attorney